

New Jersey Department of Health and Senior Services
Influenza Vaccine Update #11
December 21, 2004 – 10:00 A.M.

New Material in Bold

This memo summarizes the most recent actions taken in response to the limited supply of influenza vaccine available to the U.S. population this season. The New Jersey Department of Health and Senior Services (NJDHSS) have been engaged in many activities to ensure that only high-priority individuals receive influenza vaccine. NJDHSS has been in close contact with the Centers for Disease Control and Prevention (CDC), local health departments (LHDs), the business community, hospitals, long-term care facilities (LTCFs), Federally Qualified Health Centers (FQHCs) and trade organizations to address the many flu vaccine-related issues confronting the public health care system. Update # 10 provides information on:

- Vaccine availability
- Vaccine distribution
- Antiviral agents
- Communications
- Educational materials
- Surveillance
- Complaints
- High-priority groups and vaccine allocation
- Vaccine tracking
- Surge capacity

1. Vaccine Availability

a) Injectable Vaccine

The CDC allocated an additional 30,000 doses to New Jersey on December 20th. The following number of doses is currently available for purchase by providers:

87,716 doses of preservative-containing vaccine for individuals greater than >3 years of age.

33,671 doses of preservative-free vaccine for children 6-35 months of age.

Approximately 49,000 doses from the Vaccine for Children (VFC) program are also available. On December 17, the CDC's Advisory Committee on Immunization Practices expanded the groups of eligible children to receive VFC influenza vaccine to include VFC-eligible children who are household contacts of persons in high-risk groups, effective immediately.

b) Live Attenuated Inhaled Vaccine (FluMist)

Medimmune Inc. plans to produce 3 million doses of live attenuated inhaled vaccine (FluMist) approved for use by healthy individuals between 5 and 49 years of age. They distributed 400,000 doses per week for 5 weeks beginning in November followed by another 1 million doses in January 2005. The use of FluMist is not limited to healthcare workers (HCWs) or direct caregivers, but is available to other eligible people in the general population. NJDHSS surveyed LTCFs to assess their interest in receiving FluMist for use among health care workers (HCWs) ages 18-49 years. CDC informed NJDHSS that initially 5,200 doses would be available to New Jersey. The Department ordered the requested doses in October and they were shipped directly to LTCFs by December 3rd.

A provider may distribute FluMist doses that are shipped after November 2, 2004 without the use of a Freezebox. For these shipments, FluMist may be stored in a standard frost-free freezer through February 8, at which point it expires and should be discarded. All FluMist that was previously shipped should continue to be stored in a Freezebox. Should you have any questions regarding this information, please contact MedImmune, Inc. at 1-877-FLUMIST (1-877-358-6478).

All healthy people 5 to 49 years of age who are not pregnant can get FluMist this season. This includes most out-of-home caregivers and household contacts of children less than 6 months of age and most health-care workers. FluMist can be used in HCWs who care for severely immunocompromised patients in special care units, but caution must be exercised. For these HCWs, the flu shot is preferred because of a theoretical risk of passing the weakened live virus in FluMist to severely immunocompromised patients. Given this risk, HCWs receiving FluMist must avoid contact with severely immunocompromised patients for 7 days after being inoculated.

c) GlaxoSmithKline Fluarix vaccine manufactured in Germany

From US Department of Health and Human Services (HHS) press release, 12/7/04.

“HHS Secretary Tommy G. Thompson announced on December 7th that the Food and Drug Administration (FDA) authorized the use of GlaxoSmithKline influenza vaccine, Fluarix, in the United States under an Investigational New Drug (IND) application. Additionally, HHS has reached an agreement with the company to purchase 1.2 million doses of the vaccine for distribution to areas most in need.

Beginning this week, the Fluarix vaccine will be sent to the United States for distribution by the CDC, based on the agency's determination of communities most in need. Fluarix has not been licensed for use in the United States and will be administered under an IND application. The Fluarix vaccine being purchased by HHS has been approved by the European equivalents of the FDA, but is considered an IND because it is not currently licensed by FDA. The IND allows the investigational use of Fluarix, and HHS is

immediately purchasing 1.2 million doses that are available this month. GlaxoSmithKline (GSK) has agreed to make up to 4 million doses available under the IND.

Under an IND, patients who are offered the Fluarix vaccine must sign an informed consent form that provides important information and acknowledges that they are aware of the potential adverse effects associated with the investigational vaccine. Sponsors of INDs are required to monitor the use of the investigational product, maintain adequate records, control the supply of product, provide periodic reports to FDA regarding safety and other issues and make sure informed consent is obtained from individuals before receiving the vaccine. CDC will assist GSK with these activities.

FDA has, over the past month, reviewed extensive manufacturing and clinical information and conducted an inspection of the GSK manufacturing facility in Germany to determine that this vaccine is suitable for use under an IND. FDA reviewed GSK's proposed clinical study plan and informed consent document, as well as the clinical protocol and manufacturing data. The IND mechanism can be used in this situation because there is not enough time or information to allow U.S. licensure. These steps along with the conditions and controls required under the IND are designed to assure the product is safe for use during the current flu season. ”

Licensed vaccine manufactured by AvP is still available for allocation in New Jersey (see Sec 1.a.). If demand for this vaccine by individuals in high risk/high priority groups exceeds available supply in January, NJDHSS will request that Fluarix be made available to New Jersey residents. CDC will be contracting with a nationwide Contract Research Organization to distribute Fluarix to states in need of vaccine, which could only be used in ACIP/CDC- approved high risk/high priority individuals at contracted locations around the state. (E. Bresnitz)

2. Vaccine Distribution

To date, approximately 406,000 doses of CDC's allocation to New Jersey of injectable vaccine have been ordered and delivered to FQHCs, LTCFs, hospitals, LHDs, Institutions for the Developmentally Disabled, Vaccine for Children providers and private practices. An additional 23,000 doses have been ordered and are scheduled for delivery in January.

On December 17th, the federal Centers for Disease Control and Prevention Advisory Committee on Immunization Practices expanded the list of flu vaccine priority groups to include adults age 50 to 64, and out-of-home caregivers and household contacts of those in high-risk/high-priority groups. However, any expansion depends on flu vaccine availability in state and local health jurisdictions. Where the vaccine supply is adequate to meet the demand by current high risk/high priority individuals, public health authorities may expand priority groups as of early January.

On December 20th, NJDHSS sent out survey forms to health care providers statewide to determine if more influenza vaccine is needed for high-risk/high-priority individuals before NJDHSS decides whether to expand vaccine availability to other groups. The survey forms are being sent to local health departments, hospitals, long-term care facilities, federally qualified health centers and physicians. The survey asks if providers have extra vaccine they would like to sell, whether they would like to buy more vaccine for high-risk/high-priority patients, and whether they would purchase more vaccine if the eligibility criteria were expanded.

Surveys may be faxed to the department at: (609) 588-3642. Survey forms may also be downloaded from the department's web site at <http://www.nj.gov/health/flu/>, but cannot be filed on-line.

3. Antiviral agents in the outbreak setting

On October 19, the CDC released guidelines and recommendations for use of antiviral medications (<http://www.cdc.gov/flu/professionals/treatment/0405antiviralguide.htm>). Healthcare providers are expected to obtain antiviral agents from private pharmaceutical distributors and pharmacies. The CDC may honor a request made ONLY by State and Territorial Health Departments for antiviral agents from the Strategic National Stockpile (SNS) for use in outbreak settings.

In late October, NJDHSS sent copies of the above guidelines to LTCFs. A memo, which accompanied these guidelines, provided LTCFs with information to assist them in preventing and preparing for an outbreak of influenza in their facility. On November 5, NJDHSS provided supplemental guidelines to LTCFs for preventing and controlling an influenza outbreak. The document was distributed through the three state organizations representing these facilities.

4. Communications

- a) The NJDHSS Press Office has been fielding calls from the media daily, providing updates on the situation in New Jersey.
- b) In addition, the NJDHSS hotline had fielded approximately 23, 500 calls from the public, health care providers, and LHDs before the Emergency Call Center was closed on December 3rd, when the call volume dropped to about 50 calls per day.
- c) **NJDHSS held a teleconference on Friday, December 17th, to update providers on the vaccine supply and describe plans to conduct the survey that was distributed yesterday.**
- d) **NJDHSS issued a press release on December 20th announcing the survey to providers to assess vaccine demand and available supplies. The press release can be accessed at:**
http://nj.gov/cgi-bin/dhss/njnewsline/view_article.pl?id=2278

- e) The New Jersey State Epidemiologist has been participating on CDC/ASTHO/APHL/CSTE conference calls to review issues and conducting media interviews to describe the status of influenza and vaccine availability and distribution.

5. Educational materials

a) The Division of Mental Health Services in the Department of Human Services has developed a fact sheet on relieving mental health stress due to the vaccine shortage. It is entitled "Flu Vaccine Shortage: Coping with your fear and anxiety" and is available at: www.nj.gov/health/flu/flu vaccines shortage.pdf

b) In light of the vaccine shortage, NJDHSS continues to encourage our public health care partners to promote flu prevention messages including hand hygiene and universal respiratory precautions. Information and educational materials have been posted to the NJDHSS website and can be found at the following URLs:

Hand washing poster: www.nj.gov/health/flu/prevent_colds_and_flu.pdf

Cold vs. Flu chart: www.nj.gov/health/flu/fluorcold.shtml

If you get the flu: www.nj.gov/health/flu/flu cure info.shtml

Prevent the spread of flu: www.nj.gov/health/flu/prevent flu.shtml

c) Universal Respiratory Precautions posters were mailed to all LHDs. These posters are available in pdf format at: <http://www.nj.gov/health/flu/education.shtml>

d) A variety of additional educational materials, including guidance targeted to HCWs who care for peri- and postpartum women, have been developed by CDC:

Guidance for Prevention and Control of Influenza in the Peri- and Postpartum Settings Provides guidance for pre-, during, and after delivery, and breastfeeding by influenza-infected mothers.

<http://www.cdc.gov/flu/professionals/infectioncontrol/peri-post-settings.htm> (UPDATED 12-08-04)

Poster: Notice to Patients to Report Flu Symptoms

This 8.5" x 11" color poster can be printed, displayed and/or distributed. It emphasizes covering coughs and sneezes and the cleaning of hands.

<http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>

Personal Protective Equipment (PPE) in Healthcare Settings

Slides, video and posters demonstrating the use of PPE.

<http://www.cdc.gov/ncidod/hip/ppe/default.htm>

Questions and Answers: Information for Schools

The following link provides answers to questions commonly asked by school administrators, teachers, staff, and parents.

<http://www.cdc.gov/flu/school/qa.htm>

Other educational materials for schools can be found at

<http://www.cdc.gov/flu/groups.htm>

"Tools to Help Prevent the Spread of Flu in the Workplace" fact sheet provides links to multiple educational resources.

www.cdc.gov/flu/pdf/flu.tools.pdf

Patient Education Materials: 2004-05 Vaccine Shortage Flyers

<http://www.cdc.gov/flu/professionals/flugallery/shortageflyers.htm>

"Vaccination is Not the Only Way to Help Prevent the Flu" (available in several languages)

"Patient Screening Form: Who should and who should not get a flu shot?" (revised and available in several languages)

"Patient Screening Form for Clinics Providing FluMist (Nasal Spray) during the 2004-05 Flu Season"

The following interim CDC guidance was developed in response to questions about the role of masks for controlling influenza when suboptimal immunization of the public could increase the frequency of influenza infection.

<http://www.cdc.gov/flu/professionals/infectioncontrol/maskguidance.htm>

Interim Guidance for Influenza Diagnostic Testing During the 2004-05 Influenza Season

During the current flu season, the diminished supply of influenza vaccine could increase the demand for influenza testing. This document was developed to help clinicians determine when they should order testing. Diagnostic testing should be considered when an institutional outbreak of influenza is suspected or if test results would influence clinical decision making.

<http://www.cdc.gov/flu/professionals/diagnosis/0405testingguide.htm>

The CDC Flu Prevention Toolkit is now available. The resource for selected printable resources and supplemental materials is:

<http://www.cdc.gov/flu/toolkit/resources.htm>

Protecting Against the Flu: Advice for Caregivers of Children Less Than 6 Months Old (12-08-04)

Because children are at increased risk of getting severe illness from influenza, CDC recommends that all children 6 to 23 months old get a flu shot. However, flu vaccine is not approved for use in children less than 6 months. Also, influenza antiviral medications are not approved for use in children younger than 6 months. Because these children cannot get a vaccine or antiviral medications, but are at higher risk for serious flu-related complications, safeguarding them from influenza virus infection is especially important. This fact sheet provides advice to help protect children less than 6 months from the flu.

<http://www.cdc.gov/flu/protect/infantcare.htm>

Businesses and the Workplace (12-10-04)

Businesses, employers and employees can help prevent the spread of colds and flu in the workplace. On this page, you will find more information on preventing the flu, as well as, tools for employees and other useful materials for the workplace.

<http://www.cdc.gov/flu/workplace/>

6. Surveillance

On October 28, NJDHSS distributed guidelines to infection control professionals and LINCS epidemiologists for reporting influenza-related pediatric hospitalizations and deaths.

On November 30th, NJDHSS received a report of a culture-confirmed case of influenza A; the isolate was collected from an ambulatory patient on November 24. As of December 7th, there is initial indication of increased influenza-like activity in the state. As a result, the state is now reporting sporadic influenza activity. Surveillance data for influenza-like activity (ILI) in New Jersey can be accessed at <http://nj.gov/health/flu/surveillance.shtml>.

At the request of the CDC, states have added questions to the Behavioral Risk Factor Surveillance System (BRFSS) to help monitor the flu vaccine situation. **The CDC published several articles in MMWR on December 20th, summarizing vaccination rates nationally as of the end of November. Highlights of the published articles include:**

- Overall, 34.7% of high risk/high priority individuals had been vaccinated nationally by November 30th. New Jersey's percentage was 32.9%. Last year, 54.1 % of high priority individuals in the U.S. were vaccinated by the end of the season.
- 6 times as many high risk/high priority individuals have been vaccinated this year, compared to low risk people.
- The primary reasons high risk individuals have not received vaccine included: tried and could not get vaccine, saving vaccine for others, thought they were not eligible, thought vaccine was not needed, concerned about vaccine, lack of access and other reasons.
- About 60% of high risk adults did not try to get vaccine, many because they perceived there was a shortage.

- **The MMWR articles demonstrate a substantial need by the public for flu vaccine that has not been met: Problem: High risk/priority individuals may not be demanding vaccine from providers.**

7. Complaints

We have received only a few complaints of organizations providing vaccine to low priority individuals. Upon further investigation, these complaints have proven to be unfounded. NJDHSS will investigate all such complaints, as well as those related to potential price gouging. All complaints can be called to the NJDHSS hotline at 1-866-234-0964.

8. High-priority groups and allocation of vaccine

NJDHSS continues to require that only high risk/high priority individuals receive influenza vaccine, as delineated in former Commissioner Clifton Lacy's executive order, dated October 29, 2004. These groups include:

- All children aged 6-23 months;
- Adults aged 65 years and older;
- Persons aged 2-64 years with underlying chronic medical conditions;
- All women who will be pregnant during the influenza season;
- Residents of nursing homes and long-term care facilities;
- Children aged 6 months-18 years on chronic aspirin therapy;
- Health-care workers involved in direct patient care; and
- Out-of-home caregivers and household contacts of children aged <6 months.

During the week of January 3rd, NJDHSS will assess the responses to the survey distributed on December 20th and will decide whether, and how broadly, to expand eligibility criteria for vaccination.

If a provider has unused vaccine and wishes to sell or give that vaccine to another provider, please contact NJDHSS at 609-588-7520 and we will help to facilitate that transfer.

9. Vaccine tracking

On Friday, October 22, NJDHSS trained 22 LINCS sites to use the New Jersey Emergency Preparedness Inventory System, a web-based inventory system to track the receipt, storage, and distribution of vaccine and other medical supplies. However, NJDHSS staff has determined that this system is less than ideal for our needs. As a result, we will be using the NJ Inventory Management System that is more suited for our goals and has better reporting capabilities. NJDHSS provided instructions on using this system through the HAN. If you have any questions, please call the NJDHSS Help Desk at 1-800-883-0059.

10. Surge capacity

On October 22, NJDHSS staff met with representatives of the hospital associations to discuss issues related to surge capacity in the event of increased morbidity related to influenza this season. Surge capacity was also briefly discussed at the quarterly MEDPREP meeting held on October 25. The group discussed emergency department triage, cohorting of patients, Universal Respiratory Precautions, availability of ventilators and other issues. NJDHSS developed influenza surge capacity guidance for healthcare facilities based on best practices and currently is vetting the draft with appropriate stakeholders. These guidelines were distributed to hospitals through the trade organizations and to LHDs and EMS agencies through LINCS.

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